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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,053	SIMARD ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08272004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 10/292,413, which claims the benefit of the filing date of provisional application 60/336,968.

Claims 1-25 are currently pending and are the subject of examination in the present Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 11-16, 18 and 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-16 and 18 are ambiguous and unclear in the recitation of "essentially consisting of." The meaning of the term is not readily apparent from the specification. Does the term include substitutions, deletions additions of amino acid residues? Does the term encompass different starting or ending residues if the 'function' of the encoded segment is maintained? Clarification is required.

Claim 19 is ambiguous and unclear in the recitation of "essentially a housekeeping epitope." While the specification defines a "housekeeping epitope" as an epitope that is processed by one pathway but not another, the meaning of "essentially a housekeeping epitope" is not readily apparent. Does it mean an epitope that is processed by multiple means depending upon conditions? It is also not clear what the epitope binds to -- e.g., to MHC, to a TCR, to an antibody V-region? Also, the claim does not define what state of cellular differentiations, activation, etc., is considered "housekeeping" and what state of cellular differentiations, activation, etc., is considered to not be "housekeeping." Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-19, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al (Nature Genetics [1994] 7(4):502-508; U on form PTO-892).

The claims are drawn to an isolated nucleic acid molecule and are drafted in an open format. Claim 1 recites that the nucleic acid "comprises" a reading frame that "comprises" a first sequence that "encodes one or more segments of tumor-associated antigen SSX-2, wherein the first sequence does not encode the complete SSX-2 antigen." Accordingly, the "first sequence" reads upon a fragment of the nucleic acid molecule that encodes SSX-2. However, the claim is drawn to a reading frame "comprising" that fragment. Accordingly, the "isolated nucleic acid comprising a reading frame" reads upon the full length SSX-2 nucleic acid comprising the fragment of the "first sequence" because the full-length nucleic acid comprises any and all fragments thereof. Also, claim 1 does not define what might be or not be encoded by an "in frame second sequence." Any undefined "second sequence" could be constituted by a sequence encoding a fragment of SSX-2 antigen, which, together with the first sequence, would constitute the whole SSX-2 encoding sequence.

3. Claims 1-8, 12-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al (Nature Genetics [1994] 7(4):502-508; U on form PTO-892).

Clark teaches an isolated nucleic acid comprising a reading frame comprising a first sequence that encodes one or more segments of tumor-associated antigen SSX-2, wherein the first sequence does not encode the complete SSX-2 antigen (see entire document, Figure 4b in particular). The encoded fusion protein comprises amino acid residues 111-188 of the SSX-2 polypeptide, a fragment [claim 4] further comprising the epitopes 167-180 and 167-183 of SSX-2 [claim 2,3], accordingly possessing at least two amino acid segments having a known or predicted affinity for a same MHC receptor peptide binding cleft. The encoded SSX-2 polypeptide fragment consists of a length less that about 50% of the length of SSX-2 [claims 5-8]. The instant specification does not set forth the metes and bounds of the open term "consists essentially of." Accordingly, since the nucleic acid taught by Clark comprises at least two epitopes of SSX-2, the fragment comprises essential elements within the 111-188 fragment of SSX-2 and therefore is seen as satisfying the requirements of claims 12-16 and 18. Claim 19 is included because, while Clark is silent regarding the presence of "housekeeping epitopes" in the sequence of the encoded fusion protein, silence about a particular property does not necessarily constitute its absence. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed

subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See *In re* Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte* Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). The specification is vague regarding the definition of sequences that constitute "housekeeping epitopes." Accordingly, the fusion protein of Clark potentially comprises at least one epitope that constitutes a housekeeping epitope and the burden is upon Applicant to demonstrate that the fusion protein of Clark comprises no such epitopes.

The prior art teaching anticipates the claimed invention.

4. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Crew et al (The EMBO Journal [1995] 14(10):2333-2340; V on form PTO-892).

Crew teaches the nucleic acid encoding the SSX-1 polypeptide. Crew teaches that SSX-1 is 81% identical to SSX-2 (Abstract in particular). Accordingly, Crew teaches a nucleic acid encoding a multitude of sequences that encode one or more segments or fragments of SSX-2. In particular, the epitopes 167-180 and 167-183 of SSX-2 are identical to the same amino acid residues of SSX-1 (Figure 3 in particular). The SSX-1 nucleic acid of Crew encodes fragments of SSX-2 that are less than about 10% of the length of SSX-2 [claims 5-10]. The instant specification does not set forth the metes and bounds of the open term "consists essentially of." When applied to a polypeptide or nucleic acid compound, the term embraces substitutions/additions/deletions to the sequence that do not affect the functional properties of the sequence, such as the ability of epitopes within the sequence to bind MHC. Accordingly, the reading frame comprises sequences encoding fragments "consisting essentially of" the fragments recited in claims 11-18.

Additionally, the claims are drawn to an isolated nucleic acid molecule and are drafted in an open format. Claim 1 recites that the nucleic acid "comprises" a reading frame that "comprises" a first sequence that "encodes one or more segments of tumor-associated antigen SSX-2, wherein the first sequence does not encode the complete SSX-2 antigen." Accordingly, the "first sequence" reads upon a fragment of the nucleic acid molecule that encodes SSX-2. However, the claim is drawn to a reading frame "comprising" that fragment. Accordingly, the "isolated nucleic acid comprising a reading frame" reads upon the full length SSX-2 nucleic acid comprising the fragment of the "first sequence" because the full-length nucleic acid comprises any and all fragments thereof. Crew teaches the sequence of SSX-2 and the polypeptide encoded thereby (Figure 3 in particular). the SSX-2 nucleic acid taught by Crew comprises all the sequences, segments and fragments that are subunits of the SSX-2 polypeptide,

including a "first sequence" comprised within the reading frame that "encodes exactly amino acids 15-183 of SSX-2" [claim 17].

Claim 19 is included because, while Crew is silent regarding the presence of "housekeeping epitopes" in the sequence of the encoded fusion protein, silence about a particular property does not necessarily constitute its absence. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See *In re* Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte* Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Accordingly, the SSX-1 and SSX-2 polypeptides of Crew each potentially comprises at least one epitope that constitutes a housekeeping epitope and the burden is upon Applicant to demonstrate that the fusion protein of Clark comprises no such epitopes.

The prior art teaching anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-8, 12-16, and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (Nature Genetics [1994] 7(4):502-508; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; W on form PTO-892).

Clark et al has been discussed supra.

Clark et al does not teach operably linking the nucleic acids to a promoter sequence or immunogenic compositions.

Campbell teaches that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make attach a promoter sequence to the nucleic acid encoding the fusion polypeptide of Clark in order to express the protein and raise antibodies to it. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the peptides based on the fact that it is a conventional practice in the art to do so for further study, characterization and identification of a specific peptide and its interactions.

6. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crew et al (The EMBO Journal [1995] 14(10):2333-2340; V on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; W on form PTO-892).

Crew et al has been discussed supra.

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Campbell teaches that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make attach a promoter sequence to the nucleic acid encoding the SSX-1 or SSX-2 polypeptide of Crew in order to express the protein and raise antibodies to it. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the peptides based on the fact that it is a conventional practice in the art to do so for further study, characterization and identification of a specific peptide and its interactions.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 21, 2005

David A Saunders

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PRIMARY EXAMINER
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